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VIA E-FILING

The Honorable Sue L. Robinson
United States District Court
J. Caleb Boggs Federal Building
844 North King Street
Wilmington, DE 19801

Re: **Siemens Medical Solutions USA, Inc. v. Saint-Gobain Ceramics and Plastics, Inc., C.A. No. 07-190**

Dear Judge Robinson:

This letter constitutes defendant Saint-Gobain Ceramics and Plastics, Inc.'s ("Saint-Gobain") submission to support Saint-Gobain's requested jury charge that Siemens Medical Solutions USA, Inc. ("Siemens") bears the burden of proving by clear and convincing evidence that Saint-Gobain's LYSO crystal constitutes a legal equivalent, under the judicially created concept of the doctrine of equivalents, to the LSO crystal claimed in the asserted United States Patent No. 4,958,080 (the "'080 Patent"). This question is the fulcrum issue on which the determination of infringement here turns: does the law countenance a finding that the LYSO crystal, sold by Saint-Gobain to Philips, which crystal is itself unambiguously subject to the scope of Claim 1 of United States Patent No. 6,624,420 (the "'420 Patent"), constitutes a legal "equivalent" to the LSO crystal described in Claim 1 of the '080 Patent?

Siemens' preliminary injunction application submission relied on Siemens' reading of *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950), to argue that Saint-Gobain's LYSO crystal does constitute such an equivalent. (Plaintiff's Opening Brief in Support of Its Motion for Preliminary Injunction, D.I. 19, at 19-20). Siemens misreads and misapplies *Graver Tank* to reach that conclusion. There, the alleged "equivalent" compound had *not* been tested and examined by the United States Patent and Trademark Office (the "USPTO"), as LYSO has been here; the alleged equivalent there was not awarded patent protection as a novel and inventive compound, distinct from the earlier patented, non-identical compound, as was

LYSO here. The distinction in *Graver Tank* that the accused compound was not subject to a patent was but one of a number of distinctions drawn by Justice Jackson in affirming the conclusion that the accused compound, though not identical to the patented compound, nevertheless infringed the patent granted on the earlier compound by virtue of the doctrine of equivalents. *Graver Tank*, at 611-612. In *Graver Tank* also, the substitution of manganese for magnesium in the accused product was a known substitution among persons of ordinary skill in the art. These facts and distinctions frame the context of Siemens' infringement allegations here respecting LYSO and the true significance of the allegations that Siemens makes respecting its claim of infringement through the doctrine of equivalents.

There can be no legitimate question that Saint-Gobain's LYSO, containing approximately 10% yttrium concentration falls within the broad range of LYSO crystals (based on yttrium content) that is claimed in the '420 Patent, as to which Saint-Gobain has a license to make, use and sell LYSO. By asserting that a compound that is itself subject to a patent constitutes an equivalent to the earlier patented compound, LSO, Siemens squarely impeaches the conclusion of the USPTO that LYSO crystals containing 10% yttrium (as just one quantum point on a broader spectrum of yttrium concentration claimed in the '420 Patent) deserve patent protection.

Although Siemens argues that Saint-Gobain's LYSO is somehow a legal "equivalent" to LSO, it also contends that at some higher, undefined point on the patented spectrum of yttrium concentration in an LYSO crystal as claimed by the '420 Patent, the LYSO crystal would no longer be a legal equivalent to LSO. Siemens' argument, however, founders on the fact that Claim 1 of the '420 Patent claims a whole range of yttrium concentrations from 0.0001 to approximately 0.999%. If, as Siemens argues (and Saint-Gobain stoutly denies), the Saint-Gobain LYSO crystal with a 10% yttrium concentration constitutes a legal equivalent, then, as a direct legal and logical consequence, Claim 1 of the '420 Patent cannot, simultaneously, be valid. The reason is best and succinctly stated by the Federal Circuit in a recent *Festo* decision:

> ... [W]e have held that when a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 493 F.3d 1368, 1379-1380 (Fed. Cir. 2007). One way to make "a finding of equivalency . . . at least considerably more difficult to make out" where, as here, a non-identical compound, subject to a patent, is accused of infringing, by the doctrine of equivalents, an earlier patent, is to impose the higher "clear and convincing" standard of proof on Siemens to show equivalence.

The logic of imposing this higher standard rests on several heads of settled authority. First, all issued patents are presumed to be valid. 35 U.S.C. § 282. Both the '080 Patent and the '420 Patent are accordingly deserving of the benefit of this presumption. There is likewise no controversy that "A party challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence." *Voda v. Cordis Corp.*, 2008 U.S. App. LEXIS 17542, 23-24 (Fed. Cir. Aug. 18, 2008); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed.

Cir. 2007); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004). The burden of proving invalidity by clear and convincing evidence is equally applicable to a validity challenge to a single claim: "A party seeking to establish that particular claims are invalid must also overcome the presumption of validity in 35 U.S.C. § 282 by clear and convincing evidence." *Nystrom v. Trex Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005); citing *State Contracting & Eng'g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1067 (Fed. Cir. 2003).

These basic principles should be considered in the immediate factual context of this action. Saint-Gobain offers its LYSO crystal under a valid license from the Research Foundation of the University of Central Florida to manufacture and sell cerium doped lutetium yttrium orthosilicate, covered by Claim 1 of the '420 Patent. The '420 Patent was granted by the USPTO over the '080 Patent as prior art, not as an improvement of the '080. Deference is accordingly due the full scope of USPTO's grant of Claim 1 of the '420 Patent as written, embracing a broad range of yttrium concentrations.

By arguing that a LYSO crystal with a 10% concentration of yttrium constitutes a legal equivalent, but that not *all* LYSO crystals would constitute LSO equivalents, suggesting that at some higher level of yttrium concentration it would not assert equivalence, Siemens attempts to segment the range of yttrium concentration in LYSO that is entitled to patent protection, i.e., concede the non-equivalence to LSO at some unspecified level, from that which Siemens urges does constitute an equivalent to LSO. Siemens' argument accordingly is a disguised attack on the validity of Claim 1 of the '420 Patent, for, as Judge Nies observed, an accused product cannot simultaneously be an equivalent to an earlier, non-identical compound and "novel and inventive," thereby worthy of patent protection. *Festo,* 493 F.3d at 1379-1380.

Precisely because proof of infringement here depends entirely on a showing of the equivalence of a patented, non-identical compound with an earlier patented compound, were Siemens to prevail on a preponderance of the evidence standard to show equivalence, it would subvert the presumption of the validity of the '420 Patent on an evidentiary standard below that required by law to demonstrate such invalidity. The legal and logical inconsistency of Siemens' allegations that a patented, non-identical chemical compound infringes an earlier patent over a chemical compound require clear and convincing evidence to prove that Saint-Gobain's LYSO crystal is a legal equivalent precisely because such a finding rebuts the presumption of the '420 Patent's validity. *Voda v. Cordis Corp.*, 2008 U.S. App. LEXIS 17542, 23-24 (Fed. Cir. Aug. 18, 2008); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

Siemens' attempts to mask its assault on the validity of the '420 Patent argument as one of claim construction and a mere infringement question that depends only upon the preponderance of evidence test. The truth, however, is that the infringement claim made here depends upon and is inextricably bound up with an attack on the validity of Claim 1 of the '420 Patent. Claim 1 of the '420 Patent claims "a scintillator detector . . . comprising: a monocrystaline structure of cerium doped lutetium yttrium orthosilicate, $Ce_{2x},(Lu_{1-y}Y_y)_{2(1-x)}SiO5$ where x= approximately 0.0001 to approximately 0.05 and y= approximately 0.0001 to approximately 0.999." That claim encompasses LYSO with a 10% yttrium concentration. For

Siemens to say, as it does, that "Siemens does not and has never contended that an LYSO crystal with 85%, 70%, 50% or even 30% yttrium . . . is an equivalent to an LSO crystal" (Plaintiff's Reply Brief in Support of Its Motion for Preliminary Injunction, D.I. 55, at 11), proves only that Siemens is endeavoring to carve out of Claim 1 of the '420 Patent an LYSO crystal with certain yttrium concentrations that, according to Siemens, do not deserve patent protection. Neither this Court---nor, certainly, the jury---can rewrite Claim 1 of the '420 Patent, to change the claim to what Siemens would urge as a "valid" range of yttrium concentration in a LYSO crystal covered by the '420 Patent. And precisely where that bright line might be, between what Siemens regards as "equivalent" to the LSO claimed in the '080 Patent and the range of yttrium concentrations in an LYSO crystal that, again according to Siemens, escapes the scope of the '080 Patent under the doctrine of equivalents, Siemens does not say. Whether Siemens regards some concentrations of yttrium in an LYSO crystal to be outside the scope of the '080 Patent is significant for this action to the extent that Siemens argues that *some* LYSO crystals, depending on yttrium concentration, do constitute equivalents. That argument equates legally, logically and inescapably to be a challenge to the validity of Claim 1 of the '420 Patent.

Neither is it of moment that the Specification of the '420 Patent does not specifically identify a 10% yttrium concentration as a disclosed embodiment. There is no requirement for a patentee to delineate all embodiments in a specification. The invention protected by the patent is bounded by the *claims* of the patent, not by its specification. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). The Federal Circuit has held that when an attack on validity "simply goes over the same ground traveled by the PTO, part of the [attacker's] *burden* is to show that the PTO was wrong in its decision to grant the patent." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008); *citing Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed. Cir. 1984) (emphasis in original). There should be no doubt that the attacker's burden---here, Siemens---to make such a showing is by clear and convincing evidence in order to give the required obeisance to the validity of the '420 Patent.

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips*, at 1312; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."). It is also well settled that "a party wishing to use statements in the written description to confine or otherwise affect a patent's scope must, at the very least, point to a term or terms in the claim with which to draw in those statements. Without any claim term that is susceptible of clarification by the written description, there is no legitimate way to narrow the property right." *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1310 (Fed. Cir. 2005); citing *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). That said, Siemens' effort to distinguish between LYSO crystals, depending on their yttrium concentrations, to argue equivalence to LSO constitutes an illegitimate "way to narrow the property right" granted in Claim 1 of the '420 Patent. The '420 Patent's inventors and Saint-Gobain are each entitled to the full scope of Claim 1's grant, as written, including, at a minimum, a LYSO crystal having a 10% yttrium concentration.

Siemens argues in practical terms that the preferred embodiment in the specification, which discloses experiments using 30%Y LYSO, translates to mean that the '420 Patent covers only LYSO containing 30%Y or above. Siemens' argument flies in the face of law to the effect that in the absence of a clear and "intentional disclaimer, or disavowal, of claim scope by the inventor . . ." the specification does not limit the scope of the claims. *Phillips*, at 1316; *see also Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357 (Fed. Cir. 2006). The '420 Patent specification does *not* contain such a disclaimer and none should be imposed by this Court on the basis of Siemens' arguments.

Saint-Gobain admittedly can point to no direct authority that explicitly holds that a claim of equivalence to an earlier patented compound for a non-identical chemical compound, subject to a subsequent patent, requires proof of equivalence by clear and convincing evidence in order to preserve, appropriately, the latter patent's validity. Conversely, Saint-Gobain has found no case rejecting that conclusion, in which, for example a patented compound has been found an "equivalent" of an earlier patented compound despite the latter patenting. The plain (and remarkable) fact is that Siemens' infringement claim in the chemical context that a later patented non-identical compound is an "equivalent" to an earlier patent compound presents a novel and challenging legal issue. Proof of equivalence in this case on less than a standard of clear and convincing evidence, however, deprives the '420 Patent of the benefit of its statutory presumption of validity.

For these reasons, Saint-Gobain submits that the burden of proving that a non-identical compound, subject to independent and later patent protection as Saint-Gobain's LYSO enjoys, constitutes the legal equivalent of an earlier patented compound should be by clear and convincing evidence, the usual standard to prove invalidity, in order to preserve the evidentiary regime that exists to honor issued patents by upholding the statutory presumption of validity and thereby prevent the invalidation of issued patents on a lesser standard than that traditionally required by law.

Respectfully,

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KEF/th

cc: Jack B. Blumenfeld, Esq. (by e-mail and hand delivery)